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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,395	06/08/2001	David K. Gardner	033948-0102	7684

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[REDACTED] EXAMINER

ANGELL, JON E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1635

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8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/877,395	GARDNER ET AL.
	Examiner J. Eric Angell	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 May 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 and 34 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 and 26-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-34 are pending in the application.

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-20 and 26-33) in Paper No. 7 is acknowledged.
2. Claims 21-25 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9, 12-14, 17-20 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The instant claims encompass compositions comprising "fermented hyaluronan". However, "fermented hyaluronan" is not clearly defined. The only guidance towards the definition of "fermented hyaluronan" provided in the specification is, "By utilizing fermented HYN rather than HYN from a warm blooded vertebrate source, the ability to control the safety and stability of the HYN from different sources and batches is greatly increased" (p. 3, last paragraph), and "Fermented Hyaluronan (HYN) is obtained by any process well known in the

art. One such process is the continuous bacterial fermentation of *Streptococcus equi*" (p. 6, first paragraph), and "Typically, the molecular weight of fermented HYN is 2.3×10^6 kD" (also p. 6, first paragraph). Based on the guidance provided in the specification, it is unclear if hyaluronan (HYN) is a product of any non-warm-blooded vertebrate, or if fermented HYN is a product that produced by streptococcal fermentation of HYN, or if it is derived by other means. Without a clear definition of "fermented hyaluronan" the claims are indefinite. Furthermore, there is no disclosure that the structures of fermented HYN and HYN are different. Therefore, fermented HYN and HYN are considered to be structurally identical.

6. Claim 6 recites the limitation "the citrate" in line 1. There is insufficient antecedent basis for this limitation in the claim, as claim 1 does not recite "citrate".

7. Claim 31 recites the limitation "the media that can support can support embryo or cell development" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim, as claim 30 does not recite a medium that can support "embryo development".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyano et al. (*Theriogenology*, Vol. 41(6):1229-1305, 1994).

It is noted that without a clear definition of “fermented hyaluronan” and without any evidence disclosed in the specification that the fermented hyaluronan and hyaluronan are structurally different, it is concluded that fermented hyaluronan and hyaluronan are structurally identical. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present (MPEP § 2112). Therefore, fermented hyaluronan and hyaluronan are deemed to be identical functions based on their identical chemical structures.

Miyano teaches a mammalian culture medium comprising hyaluronan (here hyaluronic acid, which is another name for hyaluronan) and a medium that can support cell development, here Whitten’s medium (see p. 1300, under Culture Media) wherein the concentration of fermented hyaluronan is in a range of about 0.1mg/ml to about 1.0mg/ml (see p. 1302, Table 2). Although claim 17 is drawn to “fermented hyaluronan”, it is appropriate to apply the Miyano reference because hyaluronan and fermented hyaluronan are functionally identical (see above).

10. Claims 1, 2, 7-13, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Ellington et al. (U.S. Patent 6,140,121).

It is noted that without a clear definition of “fermented hyaluronan” and without any evidence disclosed in the specification that the fermented hyaluronan and hyaluronan are structurally different, it is concluded that fermented hyaluronan and hyaluronan are structurally identical. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present (MPEP § 2112). Therefore, fermented hyaluronan and hyaluronan are functionally identical based on their identical chemical structures.

Additionally, there is no evidence disclosed in the specification that recombinant human albumin and human albumin are structurally different. As mentioned above, products of identical chemical composition cannot have mutually exclusive properties. Therefore, recombinant human albumin and human albumin are functionally identical based on their identical chemical structures.

Ellington teaches a medium such as Ham's F-10, Earl's, Whitten's or PBS for culturing sperm, embryos, or embryonic stem cells (see col. 16, 13-19) comprising a macromolecule, a buffer, as well as a protein (see col. 16, lines 25-35). Ellington teaches that the macromolecule can be hyaluronic acid (see col. 13, lines 56-65), the buffer can be sodium citrate (see col. 16, line 57), and the protein can be human albumin (see col. 16, lines 25-35; and col. 13, lines 56-65). As mentioned above, although the claims are drawn to fermented hyaluronan and recombinant human albumin, hyaluronan is structurally and functionally identical to fermented hyaluronan and human albumin is structurally and functionally identical to recombinant human albumin.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-5, 10-20, 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skelnick (U.S. Patent 6,153,582) in view of Becquart (U.S. Patent 5,612,196).

Skelnick teaches a defined serum-free composition for culturing human corneal cells comprising a glycosaminoglycan, such as hyaluronic acid, in the range of .001mg/ml to 1.0g/ml; a deturgescence agent, such as albumin, in the range of .001mg/ml to 1.0g/ml; and a buffer system, such as sodium citrate, in a range of .01mM to 10mM (see col. 3, lines 52-67) in a medium that can support cell development, here MEM or TC199 (see col. 3, lines 49-51).

Skelnick teaches that the human corneal cells can be used for transplantation (see col. 1, lines 13-

15). Skelnick also teaches that non-human derived serum contains many substances capable of eliciting an immune response (see col. 3, lines 2-3).

Skelnick does not explicitly teach that that the albumin used is human albumin.

Becquart teaches a recombinant human albumin which posses all of the properties of human albumin extracted from sera (see col.3, lines 11-14). Becquart teaches that recombinantly producing human albumin removes the risk of viral contamination (see col. 1, lines 53-57) and greatly lowers the risk of immunogenic reactions when used in pharmaceutical applications (see col. 3, lines 47-49).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to modify the media of Skelnick by substituting recombinant human albumin taught by Becquart in place of albumin. The motivation to do so would have been to make a serum-free media free of non-human serum (such as albumin, a serum protein), as suggested by Skelnick and to reduce the probability of inducing an immune response (which is possible when the corneal cells are transplanted), as suggested by Skelnick (col. 3, lines 2-4) and Becquart (col. 3, lines 47-49), and further, to reduce the risk of viral contamination, as suggested by Becquart (col. 1, lines 55-57). It is noted that replacing the albumin with recombinant human albumin in the defined serum-free media of Skelnick, would produce a medium that is free of non-recombinant human albumin.

14. Claims 1-5, 10-20, 26-30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skelnick (U.S. Patent 6,153,582) in view of Becquart (U.S. Patent 5,612,196) and further in view of Stratagene (Catalog, p. 39, 1998).

Skelnick teaches a defined serum-free composition for culturing human corneal cells comprising a glycosaminoglycan, such as hyaluronic acid, in the range of .001mg/ml to 1.0g/ml; a deturgescence agent, such as albumin, in the range of .001mg/ml to 1.0g/ml; and a buffer system, such as sodium citrate, in a range of .01mM to 10mM (see col. 3, lines 52-67) in a medium that can support cell development, here MEM or TC199 (see col. 3, lines 49-51).

Skelnick teaches that the human corneal cells can be used for transplantation (see col. 1, lines 13-15). Skelnick also teaches that non-human derived serum contains many substances capable of eliciting an immune response (see col. 3, lines 2-3).

Skelnick does not explicitly teach that that the albumin used is human albumin.

Becquart teaches a recombinant human albumin which posses all of the properties of human albumin extracted from sera (see col. 3, lines 11-14). Becquart teaches that recombinantly producing human albumin removes the risk of viral contamination (see col. 1, lines 53-57) and greatly lowers the risk of immunogenic reactions when used in pharmaceutical applications (see col. 3, lines 47-49).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to modify the media of Skelnick by substituting recombinant human albumin taught by Becquart in place of albumin. The motivation to do so would have been to make a serum-free media free of non-human serum (such as albumin, a serum protein), as suggested by Skelnick and to reduce the probability of inducing an immune response (which is possible when the corneal cells are transplanted), as suggested by Skelnick (col. 3, lines 2-4) and Becquart (col. 3, lines 47-49), and further, to reduce the risk of viral contamination, as suggested by Becquart (col. 1, lines 55-57). It is noted that replacing the albumin with recombinant human albumin in

the defined serum-free media of Skelnick, would produce a medium that is free of non-recombinant human albumin.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the reagents required for making medium composition suggested by Skelnick and Bacquart (mentioned above) into a kit format with instructions as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents into a kit. Specifically, the Stratagene catalog teaches "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
May 17, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER